



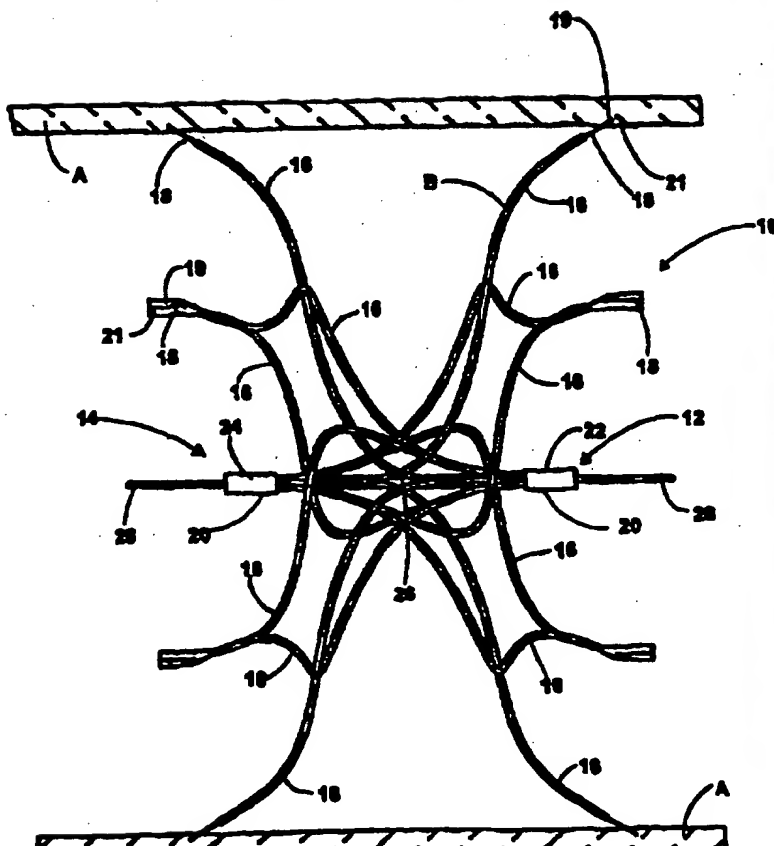
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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**08/328,629 25 October 1994 (25.10.94) US**(71) Applicant: **SCIMED LIFE SYSTEMS, INC. [US/US]; One Scimed Place, Maple Grove, MN 55311-1566 (US).**(72) Inventor: **SMITH, Scott, R.; 6950 County Road 10, Chaska, MN 55318 (US).**(74) Agents: **GAFNER, Peter, J. et al.; One Scimed Place, Mail Stop A150, Maple Grove, MN 55311-1566 (US).**(81) Designated States: **CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).****Published***With international search report.**Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.*(54) Title: **REMOVABLE THROMBUS FILTER**

## (57) Abstract

A thrombus filter configured for placement within a blood vessel lumen. The filter having a longitudinal axis. The filter includes first and second units, each unit including a plurality of elongated struts. Each strut has a joining end where the respective struts of each unit are joined together. Each strut also has a free end opposite the joining end. The struts have at least two curves such that in a longitudinal planar projection of the filter, each strut has a first direction of curvature proximate the joining end and an opposite direction of curvature closer to the free end. In a transverse planar projection of the filter, the strut has a first direction of curvature proximate the joining and an opposite direction of curvature closer to the free end. The units can be coupled together in opposition such that the free ends of the struts of the first unit are generally oriented in a first longitudinal direction and the free ends of the struts of the second unit are generally oriented in the opposite longitudinal direction.



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## REMOVABLE THROMBUS FILTER

Background of the Invention

The present invention pertains to thrombus filters. In particular, the present invention relates to thrombus filters which can be securely affixed at a selected location in the vascular system and removed when no longer required.

In recent years, pulmonary embolism has become an increasingly common medical emergency. Pulmonary embolisms may be caused by venous thrombosis, which in turn may be caused by blood flow retention, venous intima damage or coagulation abnormalities. Emergency or prophylactic treatments for these conditions includes anti-coagulant therapy, thrombolytic therapy, thrombectomy and inferior vena cava blocking procedures.

Among these therapeutic options, when an inferior vena cava blocking procedure is selected, one option is to perform a laparotomy under general anesthesia during which the inferior vena cava is ligated, sutured and shortened, or clipped. A laparotomy however, requires a general anesthetic and is susceptible to thrombosis formation due to the discontinuation of anti-coagulate therapy prior to surgery. Another option is to intravenously insert a thrombus filter into the inferior vena cava which requires a local anesthetic. Percutaneous filter insertion is now widely employed since it requires only a local anesthetic. However, such filters become affixed in the inner vena cava wall by neointimal

hyperplasia within two or three weeks after being implanted, after which they cannot be removed percutaneously.

Prior thrombus filters which may be removed percutaneously have included generally linear or column-like struts which tend to transfer forces along the longitudinal axis of the struts. If the vessel is compressed asymmetrically, the filter elongates forcing the struts into the vessel wall which may damage the vessel.

10

#### Summary of the Invention

The present invention pertains to an improved thrombus filter having struts configured to reduce the transmission of force along their longitudinal axes. The filter in accordance with the present invention provides struts which behave more as cantilevered beams than those filters which have struts tending to transfer forces primarily along the struts' longitudinal axes.

In an embodiment of the thrombus filter for placement within a blood vessel lumen, in accordance with the present invention, the filter includes a longitudinal axis. The filter also includes first and second units, each unit including a plurality of elongated struts. Each strut has a joining end where the respective struts of each unit are joined together. Each strut has a free end opposite the joining end. The struts extend generally radially outward

from the longitudinal axis of the filter and generally longitudinally.

Each strut has at least two curves such that in a longitudinal planar projection of the filter each strut has a first direction of curvature proximate the joining end and an opposite direction of curvature closer to the free end. In a transverse planar projection of the filter, each strut has a first direction of curvature proximate the joining end and an opposite direction of curvature closer to the free end.

10 The first and second units are coupled together in opposition such that the free ends of the struts of the first unit are generally oriented in a first longitudinal direction and the free ends of the struts of the second unit are generally oriented in the opposite longitudinal direction.

15 Several couplings are available to releasably couple the first and second units together.

The free ends of the struts can include a sharpened anchoring tip and an adjacent flexible pad. The filter may also include a stream lining sheath covering the struts proximate the joining ends to reduce intraluminal blood flow turbulence.

#### Description of the Drawings

Figure 1 is perspective view of a filter in accordance with the present invention;

Figure 2 is side view of the filter in accordance with the present invention;

Figure 3 is an end view of the filter in accordance with the present invention;

5      Figure 4 is a cross sectional view of a coupling for coupling first and second units of the filter together;

Figure 5 is a cross sectional view of an alternate embodiment of the coupling for coupling the first and second units of the filter together;

10      Figure 6 is cross sectional view of another alternate embodiment of the coupling for coupling the first and second unit of the filter together;

Figure 7 is a cross sectional view of yet another alternate embodiment of the coupling for coupling the first  
15 and second units of the filter together;

Figure 8 is perspective view of a free end of a strut of the filter made in accordance with the present invention;

Figure 9 is a perspective view of an alternate embodiment of the free end of the strut of the filter made in accordance  
20 with the present invention;

Figure 10 is side view of an alternate embodiment of the filter in accordance with the present invention including stream lining;

Figure 11 is a transverse cross sectional view of a hub  
25 in accordance with the present invention; and

Figure 12 is a transverse cross sectional view of an alternate hub in accordance with the present invention.

Detailed Description of Drawings

5 Referring now to the drawings wherein like reference numerals refer to like elements throughout the several views, Figure 1 shows a perspective view of a thrombus filter in accordance with the present invention and generally referred to by the numeral 10. Thrombus filter 10 includes first and  
10 second units 12 and 14, respectively. Each unit 12 and 14 includes a plurality of struts 16. Each strut includes a free end 18 and a joining end 20. Free ends 18 include a sharpened portion 19 and an adjacent flexible pad portion 21. The joining ends 20 of struts 16 of first unit 12 are joined at a  
15 hub 22 and the joining ends 20 of the respective struts 16 of second unit 14 are joined at a hub 24. Hubs 22 and 24 are generally aligned along the longitudinal axis of the filter and are fastened together by coupling 26.

Struts 16 of first unit 12 generally radiate from hub 22  
20 away from the longitudinal axis of filter 10 and longitudinally in a direction toward hub 24 of second unit 14. Similarly, struts 16 of second unit 14 generally radiates from hub 24 away from the longitudinal axis of filter 10 and generally longitudinally toward hub 22 of first unit 12.  
25 Thus, first unit 12 is coupled in opposition to second unit 14 such that free ends 18 of struts 16 of first unit 12 are

generally oriented in the opposite direction from free ends 18 of struts 16 of second unit 14.

Filter 10 also preferably includes two oppositely disposed hooks 28. One hook 28 is attached to hub 22 of first unit 12 and generally extend longitudinally in the opposite direction as struts 16 of first unit 12. Likewise, hook 28 of second unit 14 is connected to and extends from hub 24 and generally longitudinally in the opposite direction as struts 16 extends from hub 24.

10 Filter 10 may be compressed elastically in a transversed direction and placed in a sheath or catheter lumen. After compression, filter 10 may be delivered to a deployment cite within a vessel lumen by percutaneous catheterization. Within the catheter, the longitudinal axis of filter 10 is generally  
15 aligned with, or approximately parallel to the longitudinal axis of the vessel lumen. When the distal end of the catheter reaches the deployment site within the vessel lumen, compressed filter 10 is released from the sheath or catheter where it expands transversely until the free ends 18 of strut  
20 16 reach the side wall of the vessel lumen.

To allow filter 10 to undergo transverse elastic compression, struts 16 are preferably formed from nitinol wire. Other shaped memory alloy wires and super elastic metal wires may be used as well as stainless steel, tungsten,  
25 platinum, and chromium alloy wires. In a preferred embodiment, struts 16 are formed from 0.011 inch diameter



nitinol wire having a portion proximate free ends 18 having a diameter of 0.015 to improve visibility and strength, and a portion proximate joining end 20 having a diameter of between 0.012 to 0.015 inch to improve strength and fatigue performance at the hubs 22 and 24. It can be appreciated that the diameter of the wire can be varied according to the type of wire used and the particular configuration of filter 10. The wires can be formed by heat setting within a rigid mold as well as by other methods known in the art.

10 Struts 16, in accordance with the present invention have been configured to respond more like cantilevered beams than as columns. That is, significant bending and torsional forces are distributed along struts 16, rather than forces being primarily transmitted along the longitudinal axes of struts 16. By configuring struts 16 to act more as cantilevered beams rather than as columns, it is believed that the struts will act more independently. By acting independently, struts 16 transmit less force to hubs 22 and 24 and other struts 16, especially those forces tending to rotate filter 10 transversely within a vessel lumen.

Several criteria are taken into account in the design of struts 16. Each strut 16 should be configured and formed of material which enables struts 16 to be collapsed for delivery to a deployment location within a vessel lumen. Struts 16, however, should not produce transverse or longitudinal forces which are so great that free ends 18 of struts 16 damage the

vessel wall. Upon deployment of filter 10, struts 16 should be spaced closely enough to intercept thrombus within the range of about 3.0 millimeters to 3.0 centimeters in length, yet not obstruct the vessel so much that excess turbulence is created. Excess turbulence can lead to the formation of additional thrombus. To allow percutaneous removable of filter 10, struts 16 should be configured so that they have a minimum of contact with the vessel wall even when the vessel is compressed axially or radially. If struts 16 come in contact with the vessel wall for an extended period of time neointimal hyperplasia can grow over struts 16, embedding them in the vessel wall. The length and diameter of filter 10 must also be appropriate to the particular application. For example, when deploying filter 10 within the inferior vena cava between the iliac vein and the renal vein, the typical length of the uncompressed filter can be between about 3.0 to 4.0 centimeters in length and about 1.5 to 3.5 centimeters in diameter.

Figure 2 shows a side view of a filter 10 deployed within a vessel lumen A. For purposed of describing the shape of strut 16, it is assumed that vessel lumen A is cylindrical and that the longitudinal axis of vessel lumen A is coincident with the longitudinal axis of filter 10. In particular, this view is a longitudinal planar projection of filter 10 within lumen A. As can be seen with particular clarity by reference to the strut 16 labeled with a "B", the strut has at least two

curves such that in the longitudinal planar projection of the filter the strut has a first direction of curvature proximate joining end 20 and an opposite direction of curvature closer to free end 18. In particular, the strut 16 referred to by the letter "B" extends from hub 24 generally longitudinally and then curves in a transverse direction away from the longitudinal axis of filter 10. The strut 16 then curves in a longitudinal direction away from hub 24 closer to free end 18 of strut 16. Strut 16 as shown in Figure 2 begins to immediately curve transversely from hub 24. Strut 16 may, however, first extend longitudinally from hub 24 prior to curving transversely.

In view of the perspective from which struts 16 are viewed in Figure 2, they appear to have various shapes. Struts 16, as shown in Figure 2, however, are in fact generally the same shape. For convenience of manufacture, each of the struts may be formed in the same shape, but in accordance with the present invention, they need not so long as the curvature of struts 16 provides the desired performance characteristics.

Preferably, first unit 12 includes six struts 16 and second unit 14 include six struts 16. Fewer or more struts per unit may be used in accordance with the present invention. Varying the number of struts can, however, affect the ability of filter 10 to filter thrombus from the vessel and to retain its position within the vessel.

As shown in Figure 2, sharpened portions 19 of strut free ends 18 penetrate the wall of vessel lumen A. Further penetration is resisted by pads 21 abutting the vessel wall.

Figure 3 is an end view of filter 10 deployed within the vessel A. Specifically, Figure 3 shows a transverse planar projection of an end of filter 10. As can be seen, each of the six struts 16 of first and second units 12 and 14, respectively are disposed around the longitudinal axis of filter 10 at approximately even 60 degree intervals. In this view, each strut 16 has a first direction of curvature proximate hubs 22 and 24 respectively and an opposite direction of curvature closer to free ends 18. In particular, each strut 16 extends transversely from the longitudinal axis, then curves in a spiral-like fashion in a first direction (not necessarily the same direction) generally around the longitudinal axis of filter 10. Closer to free ends 18 of struts 16, struts 16 curve in a direction opposite the first direction relative to the longitudinal axis of filter 10.

In view of the complexity of the geometry of each strut 16, the following table is provided to define a typical strut 16 in cylindrical coordinates. Each row in the table defines a point along the center line of strut 16, the point in the first row being at the extreme joining end 20 of strut 16 and point in the last row being at the extreme free end 18 of strut 16. Each of the remaining rows identify intermediate points along a center line of strut 16. It should be

appreciated, however, that the strut 16 defined by the tabulated coordinates is representative only and that numerous alternate geometric configurations may be made in accordance with the present invention.

5       Cylindrical coordinates are an extension of two dimensional polar coordinates to include a third or longitudinal dimension Z. When describing the typical strut 16 in the table, the longitudinal or Z axis of the cylindrical coordinates has been chosen to be coincident with the  
10 longitudinal axis of filter 10. In the table, the first column is the radial distance R in inches from the Z axis to the center line of strut 16. The second column is the angular distance  $\theta$  from a reference line and the third column is linear distance Z perpendicular to a plane including the  
15 referenced line. The coordinates in the table assume an initial radial offset of joining end 20 from the longitudinal axis of 0.011 inches.

	R	$\theta$	Z
	0.011000	0.000000°	0.000000
20	0.011000	0.000000°	0.025000
	0.025000	0.000000°	0.100000
	0.025000	10.374822°	0.250000
	0.452243	54.969992°	0.250000
	0.669958	90.000000°	0.553000
25	0.730495	90.000000°	0.636188

Figure 4 shows a side view of coupling 26. Coupling 26 includes a first wire 30 extending generally longitudinally from hub 24 of second unit 14 toward hub 22 and a second wire 32 extending generally longitudinally from hub 22 of first unit 12 toward hub 24. An end of wire 30 opposite hub 22 is formed into a helix or coil 34. Similarly, an end of wire 32 opposite hub 24 is formed into a coil or helix shape 36. A portion of wire 30 extends through helix 36 and a portion of wire 32 extends through helix 34 to couple wires 30 to wire 32 and consequently first unit 12 to second unit 14 respectively. Coils 34 and 36 must be rigid enough to resist premature uncoupling and flexible enough to uncouple when hooks 28 are pulled in opposite longitudinal directions.

Figure 5 shows an alternate coupling 40. Coupling 40 includes a first wire 42 extending from hub 22 of first unit 12 like wire 30. Coupling 40 includes a second wire 44 extending from hub 24 of second unit 14 similarly to wire 32. A tube 46 is attached, by adhesive or other suitable means, to an end of wire 42 opposite hub 22. Tube 46 may include a crimp 48 resiliently engageable with a narrowed portion 50 of wire 44. Alternately, tube 46 may include an expanded portion engageable with an expanded end of wire 44. Tube 46 must be rigid enough to prevent premature uncoupling, however, tube 46 must be flexible enough to allow wire 44 to be removed from tube 46 when hooks 28 are pulled in opposite longitudinal directions.

Figure 6 is a cross sectional view of another alternate coupling 52 taken along the longitudinal axis of the filter. Coupling 52 includes a first wire 54 extending from hub 22 of first unit 12 longitudinally toward hub 24 of second unit 14 and a second wire 56 extending longitudinally from hub 24 of second unit 14 toward hub 22. A tube 58 is attached by adhesive or other suitable means to an end of wire 54 opposite hub 22. A notch 60 extends through a side wall of tube 58. Wire 56 includes a bend 61 which can resiliently engage notch 60 when wire 56 is inserted into tube 58. Coupling 52 may be uncoupled by pulling hooks 28 in an opposite longitudinal direction. Wires 54 and 56 and tube 58 should be sufficiently strong to resist premature uncoupling. They may, for example, be made from stainless steel or a similarly durable material. Wire 56 must be resilient enough to engage notch 60 when wire 56 is inserted into tube 58, but rigid enough that premature uncoupling is avoided.

Figure 7 shows still another alternate embodiment of a coupling 62. Coupling 62 includes a first wire 64 extending generally longitudinally from hub 22 of first unit 12 toward hub 24 of second unit 14, and a wire 66 extending from hub 24 generally longitudinally toward hub 22. The end of wire 64 opposite 22 and the end of wire 66 opposite hub 24 overlap and are coupled by a heat shrink wrap 68, such as polytetrafluoroethylene (PTFE). An adhesive 70 bonds heat shrink wrap 68 to wire 66. When hooks 28 of hubs 22 and 24

are pulled in opposite directions, wire 64 is pulled away from wire 66 and shrink wrap 68. Heat wrap 68 remains adhered to wire 66. Shrink wrap 68 must be sufficiently strong and adhesive to prevent premature uncoupling of wires 64 and 66.

5        Figure 8 is a perspective view of free end 18 of strut 16 including sharpened portion 19 and adjacent flexible pad portion 21. Sharpened portion 19 and pad 21 may be formed integrally with strut 16. This may be accomplished, by, for example, flattening free end 18 of strut 16. Flattened free  
10    end 18 can be divided by cutting it into two portions. One of the portions can be further cut to form sharpened portion 19 and the other portion bent toward the longitudinal axis of filter 10 to form pad 21. It can be appreciated that other techniques may be used in accordance with the present  
15    invention to form integral sharpened portion 19 and pad 21. Further, it should be understood that sharpened portion 19 and pad 21 may be formed separately and subsequently connected to free end 18 of strut 16 by adhesive, welding or other suitable means.

20        Figure 9 shows an alternate embodiment of free end 18 of strut 16 which includes a sharpened portion 72 and pad 74. Sharpened portion 72 and pad 74 can be formed as discussed in the preceding paragraph with respect to sharpened portion 19 and pad 21. Pad 74 is preferably more flexible than sharpened  
25    portion 72. This may be accomplished by, for example, flattening pad 74 more than sharpened portion 72. Pad 74 is



also preferably longer than sharpened portion 72. When unstressed, pad 74 can lie in the same plane as portion 72.

Figure 10 shows filter 10 including a stream lined encapsulation covering 76 over a portion of struts 16 proximate the longitudinal axis of filter 10. Stream lining of this region of filter 10 is intended to reduce the turbulence near the longitudinal axis of filter 10. The stream lined encapsulation 76 must be formed from a material which is sufficiently durable to survive expansion and contraction of filter 10, yet flexible enough to allow independent flexing of struts 16. Stream line encapsulation 76 may be formed from a heparin loaded collagen, low durometer polyurethane or other similarly suitable material.

Figure 11 is a transverse cross sectional view of hub 22, which is essentially similar to hub 24. As shown in Figure 11, joining ends 20 of struts 16 are arranged around hook 28 within a tube 78. It should be noted that hook 28 may be an integral extension of wire 30 of coupling 26. Wire 32 of coupling 26 of hub 24 and the other coupling wires of the alternate coupling embodiments may be similarly integrally formed. If these corresponding wires are not integrally formed an end of each wire can extend into the respective hub to be joined with joining ends 20 like hook 28 shown in Figure 11. Tube 78 can be a hypotube or other similarly suitable member. Within tube 78 joining ends 20 and hook 28 may be

welded together, crimped, diffusion bonded, press fit, swagged or held together by other suitable means.

Figure 12 is a transverse cross sectional view of an alternate embodiment of hub 22 including a tubular member 80 which has been compressed around joining ends 20 of strut 16 and hook 28. Compression of tube 80 causes a deformation of the circular cross sections of ends 20 and hook 28 to form an abutting planar sides between ends 20 and hook 28. Like the embodiment of hub 22 described in the previous paragraph, the respective hooks and wires may be formed integrally or separately and attached to hub 22 accordingly. Any of the joining methods mentioned above such as welding may be used in addition to compressing tube 80.

In use, it is important to measure the inside diameter of the patient's vessel so that a filter having the appropriate diameter is selected. If a filter is undersized there is a risk that it could migrate within the vessel lumen. If filter is oversized it may put undue stress on the vessel wall. A filter having an unstressed diameter equal to approximately 1.3 times the diameter of the vessel into which it is planted has been found to be desirable. This ratio is exemplary only, it being understood that the actual ratio will depend on the particular configuration of struts 16 and the material used to form them.

The thrombus filter can be delivered to a deployment site within a vessel lumen by compressing the filter into a sheath

or a catheter lumen. The distal end of the catheter is manipulated to a location within the patient's vessel where the filter 10 is to be deployed such that the longitudinal axis of filter 10 is generally coincident or parallel to the longitudinal axis of the vessel. Filter 10 is then urged from the distal end of the catheter lumen into the patient's vessel lumen. Upon release from the catheter lumen, strut 16 expands generally transversely to the longitudinal axis of filter 10 such that sharpened portions 19 penetrate the vessel lumen wall while pads 21 limit the extent of the penetration.

When it becomes necessary or desirable to remove the filter, the following procedure can be followed. Recovery devices can be inserted percutaneously and threaded through endovenous routes to opposite ends of filter 10. The devices must include means for attaching to hooks 28, such as clamps, loops, hooks, or similar means. One device is attached to each hook 28 and the devices are withdrawn in opposite directions such that first and second units 12 and 14 are pulled apart and uncoupled from each other. First and second units 12 and 14 respectively are then withdrawn from the body.

Numerous characteristics and advantages of the invention covered by this document have been set forth in the foregoing description. It will be understood, however, that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of parts without exceeding the scope of

the invention. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. A thrombus filter configured for placement within a blood vessel lumen, and having a longitudinal axis, the filter comprising:

first and second units, each unit including a plurality of elongated struts, each strut having a joining end where the respective struts of each unit are joined together, each strut having a free end opposite the joining end, and each strut having at least two curves such that in a longitudinal planar projection of the filter each strut has a first direction of curvature proximate the joining end and an opposite direction of curvature closer to the free end; and

the units are coupled together in opposition such that the free ends of the struts of the first unit are generally oriented in a first longitudinal direction and the free ends of the struts of the second unit are generally oriented in the opposite longitudinal direction.

2. A filter in accordance with claim 1, wherein, in a transverse planar projection of the filter, the strut has a first direction or curvature proximate the joining end and an opposite direction of curvature closer to the free end.

3. A filter in accordance with claim 1, wherein the free end of the strut includes a sharp anchoring tip and an adjacent flexible pad.

4. A filter in accordance with claim 1, further comprising a sheath covering the struts proximate the joining ends providing stream lining of the filter to reduce intraluminal blood flow turbulence.

5. A thrombus filter for placement within a blood vessel lumen, having a longitudinal axis, the filter comprising:

first and second units, each including a plurality of a elongated struts, each strut having a joining end and a free end, wherein the respective struts of each unit are joined together generally about the longitudinal axis of the filter at the joining ends;

each strut of the first unit extends from the joining end in generally the same longitudinal direction and then curves in a transverse direction away from the longitudinal axis and then curves in a longitudinal direction closer to the free end;

each strut of the second unit extends from the joining end in generally the same longitudinal direction and then curves in a transverse direction away from the longitudinal

axis and then turns in a longitudinal direction closer to the free end; and

the first and second units being coupled in opposition such that the free ends of the first unit struts are generally oriented in a first longitudinal direction and the free ends of the second unit struts are oriented generally in the opposite direction.

6. A filter in accordance with claim 5, wherein as each strut extends transversely from the longitudinal axis, the strut curves in a spiral-like fashion in a first direction generally around the longitudinal axis of the filter.

7. A filter in accordance with claim 6, wherein closer to the free end of the struts, the strut curves in a direction opposite the first direction relative to the longitudinal axis of the filter.

8. A filter in accordance with claim 5, wherein the free end of the strut includes a sharp anchoring tip and adjacent flexible pad.

9. A filter in accordance with claim 5, further comprising a sheath covering the struts proximate the joining ends providing streamlining of the filter to reduce intraluminal blood flow turbulence.

10. A thrombus filter for placement within a blood vessel, having a longitudinal axis, the filter comprising:

first and second units, each including a plurality of elongated struts, each strut having a joining end and a free end, wherein the respective struts of each unit are joined together generally about the longitudinal axis of the filter at the joining ends;

each strut of the first unit extends from the joining end in generally the same longitudinal direction and then curves in a transverse direction away from the longitudinal axis;

each strut of the second unit extends from the joining end in generally the same longitudinal direction and then curves in a transverse direction away from the longitudinal axis; and

the first and second units being coupled in opposition such that the free ends of the first unit struts are generally oriented in a first longitudinal direction and the free ends of the second unit struts are oriented generally in the opposite direction.

11. A filter in accordance with claim 10, wherein as each strut extends transversely from the longitudinal axis, the strut curves in a spiral-like fashion in the first direction generally around the longitudinal axis of the filter.



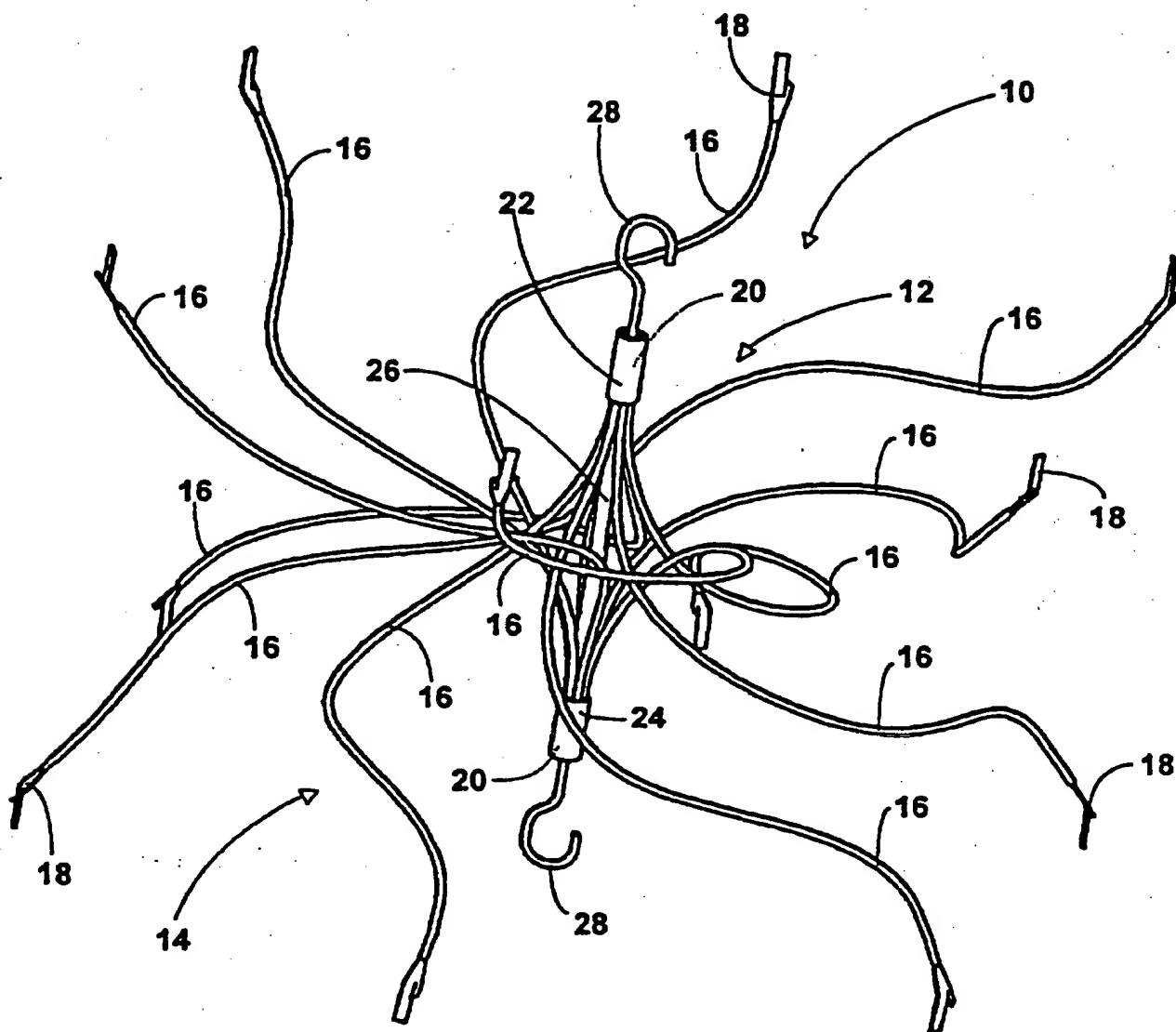
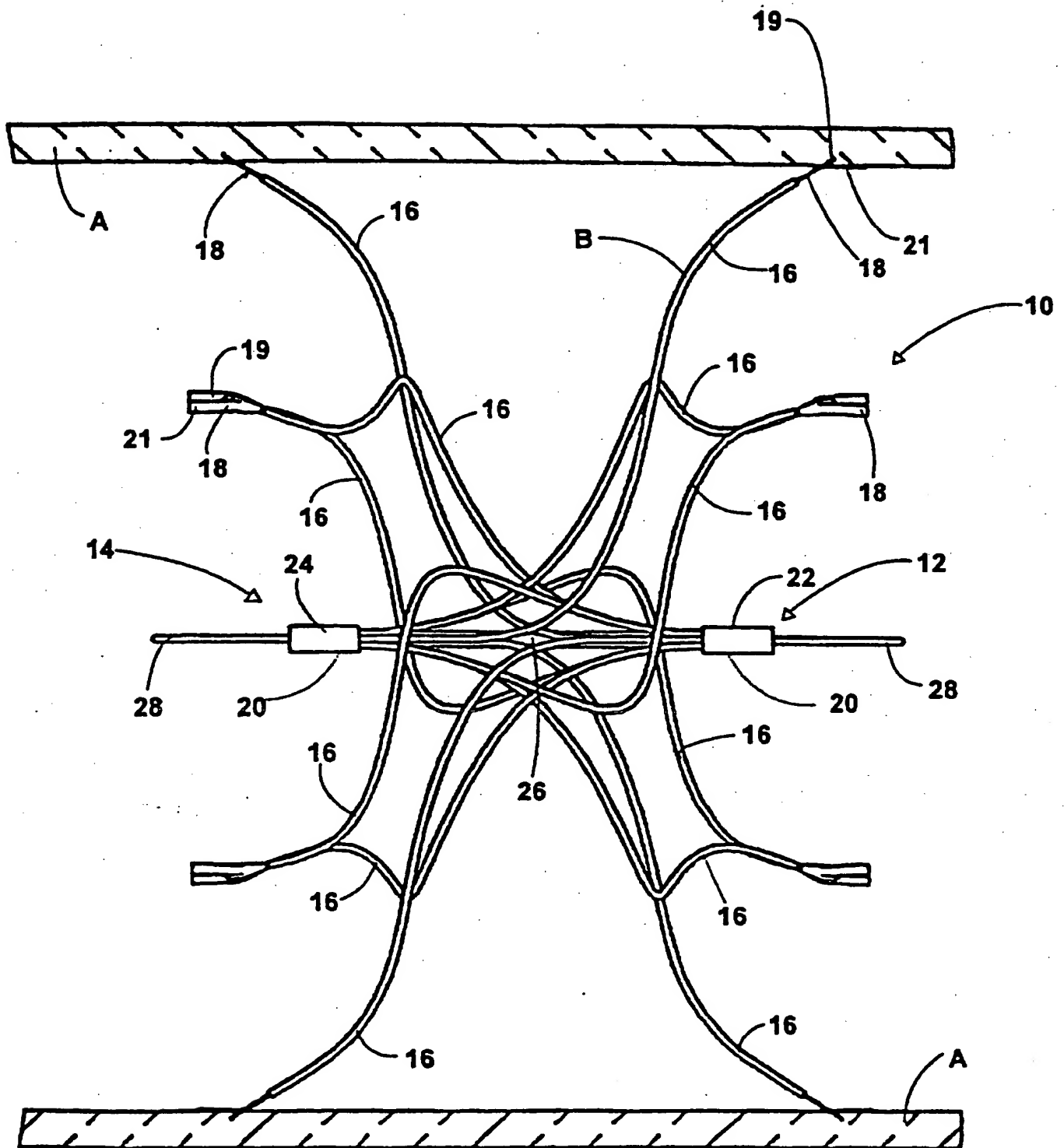


Fig. 1

12. A filter in accordance with claim 11, wherein closer to the free end of the struts, the strut curves in a direction opposite the first direction relative to the longitudinal axis of the filter.

**Fig. 2**

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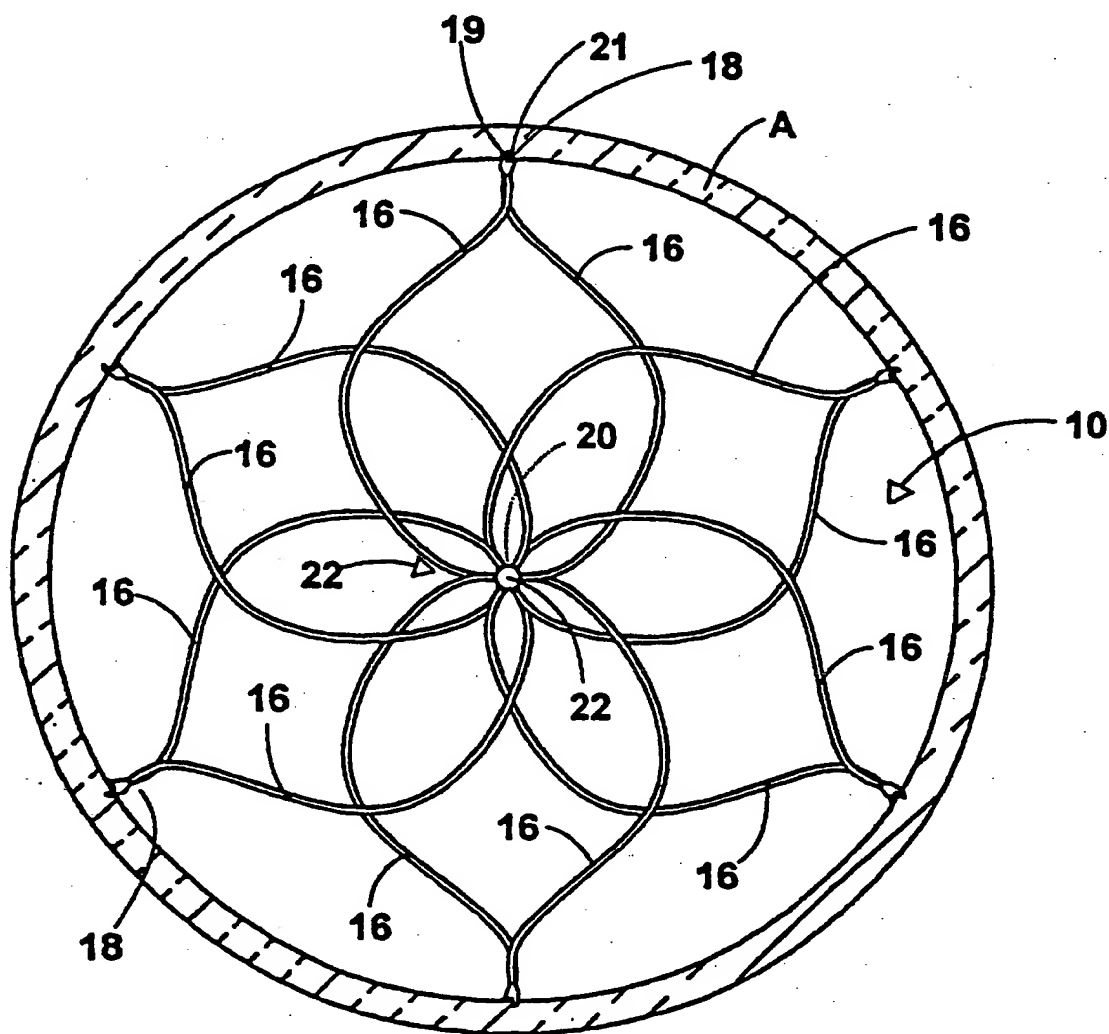


Fig. 3

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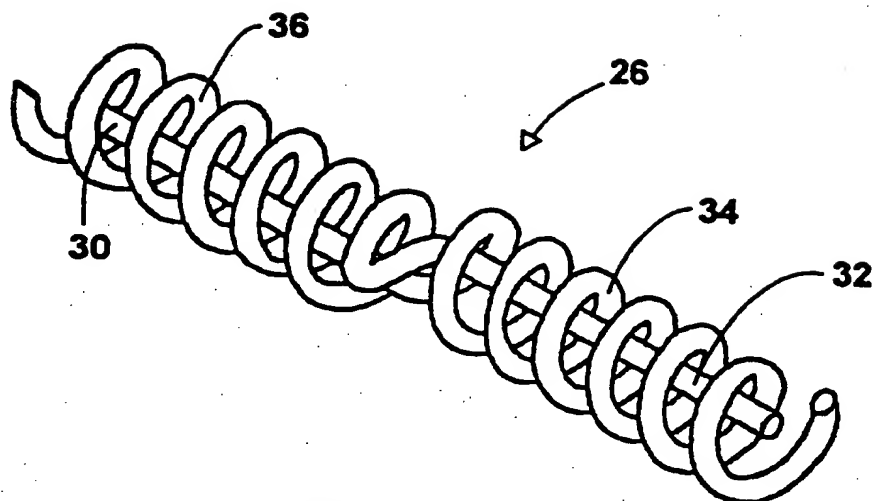


Fig. 4

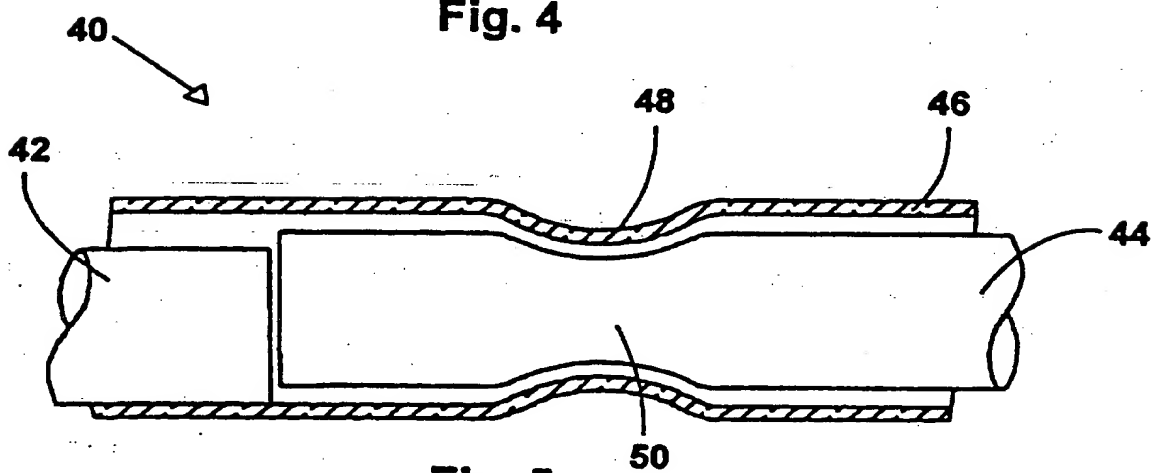


Fig. 5

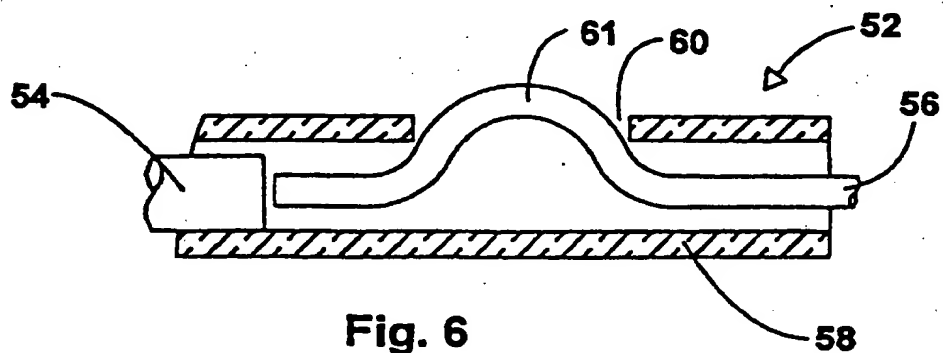


Fig. 6

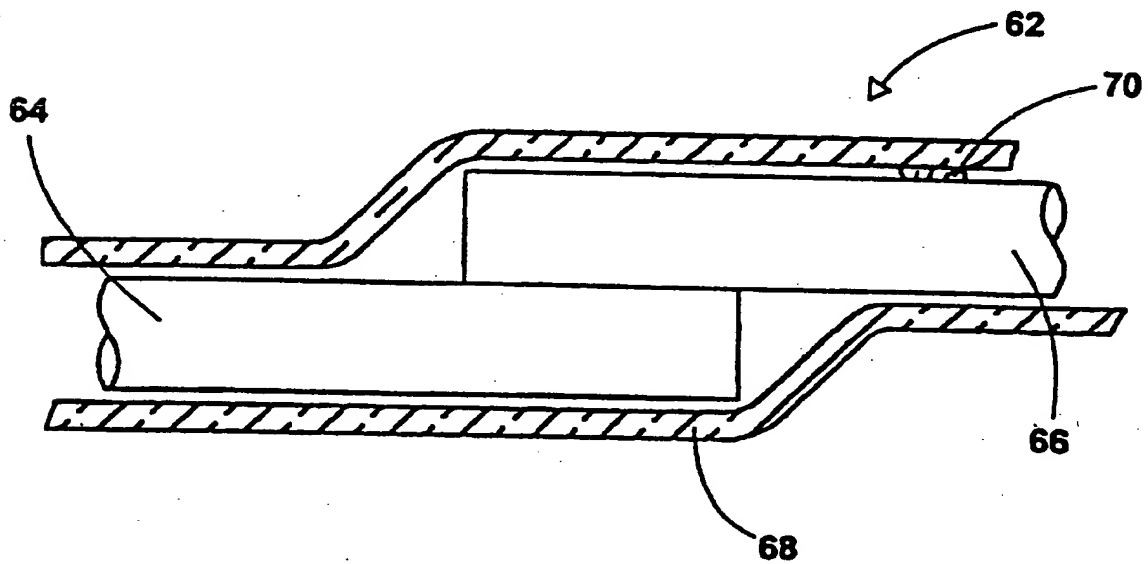


Fig. 7

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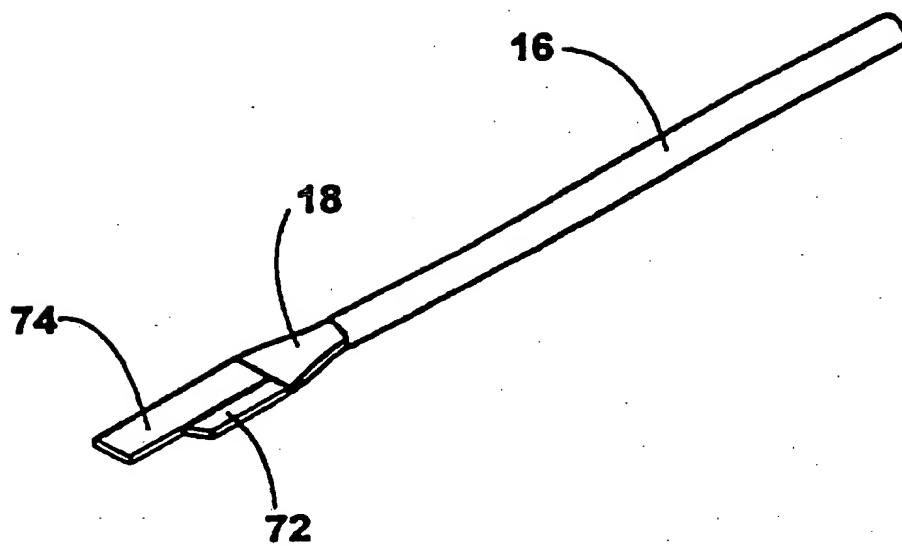


Fig. 9

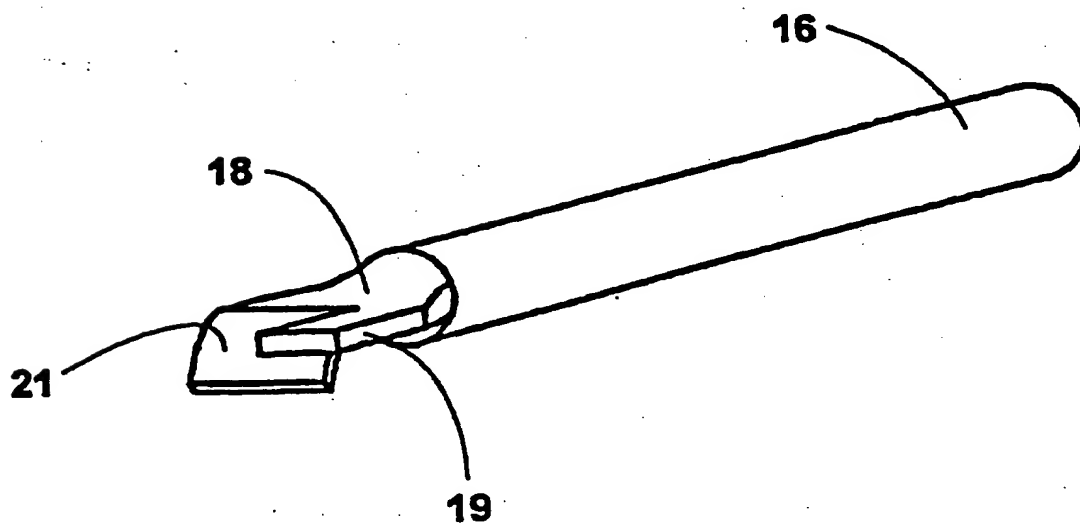


Fig. 8





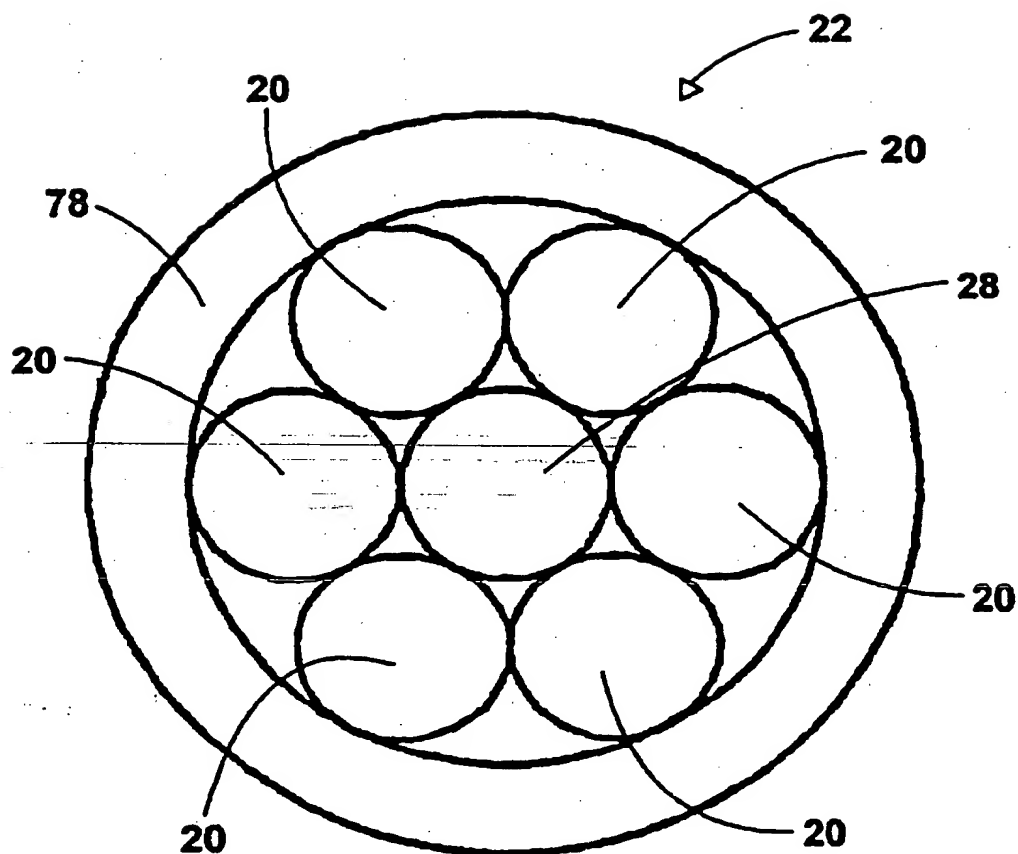


Fig. 11

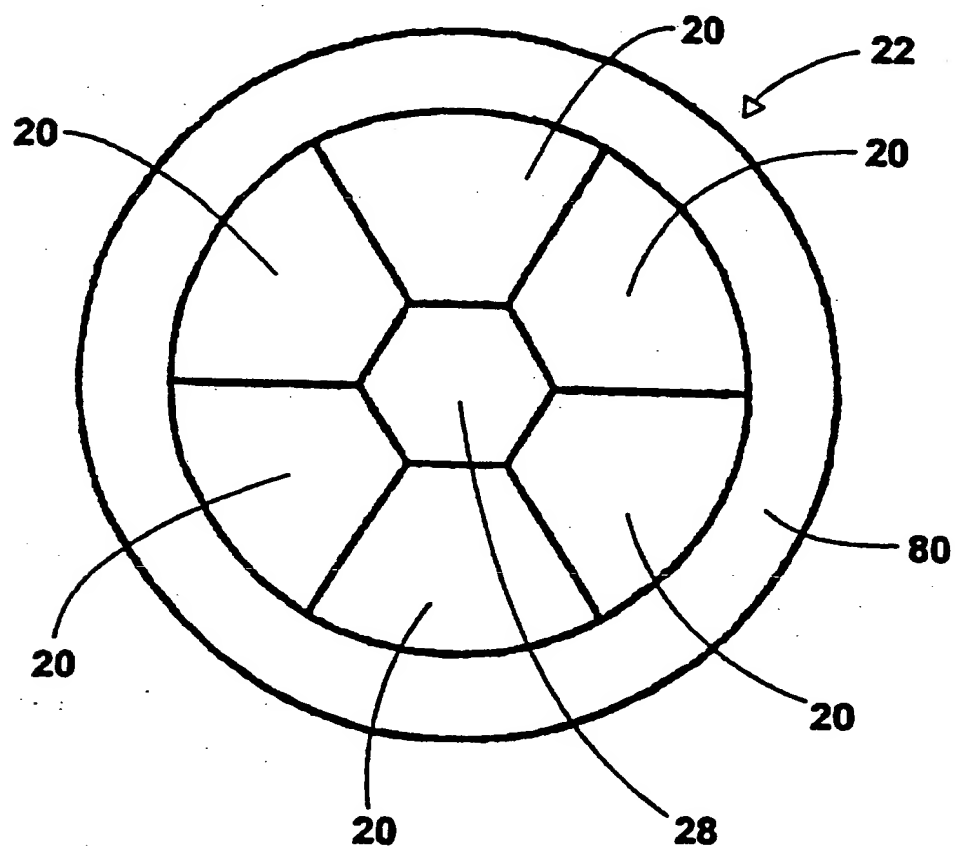


Fig. 12

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 95/13680

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 6 A61F2/01

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	FR,A,2 699 810 (CARDIAL) 1 July 1994 see page 3, line 15 - page 4, line 10; figures	1-12
Y	FR,A,2 652 267 (PROTHIA) 29 March 1991 see page 6, line 21 - line 24; figures 4,6	1-12
A	GB,A,2 276 325 (SCIMED LIFE SYSTEMS) 28 September 1994 see abstract	1,4,5,9, 10
A	FR,A,2 573 646 (CELSA) 30 May 1986 see figures 7-10	1-3,5,8, 10,12
	-/--	

☒ Further documents are listed in the continuation of box C. ☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

16 February 1996

Date of mailing of the international search report

07.03.96

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk

Authorized officer

International Application No

PCT/US 95/13680

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A,5 059 205 (F.O. EL-NOUNOU ET AL.) 22 October 1991 see column 3, line 56 - column 4, line 24; figures 1,2,4,5 -----	3,8

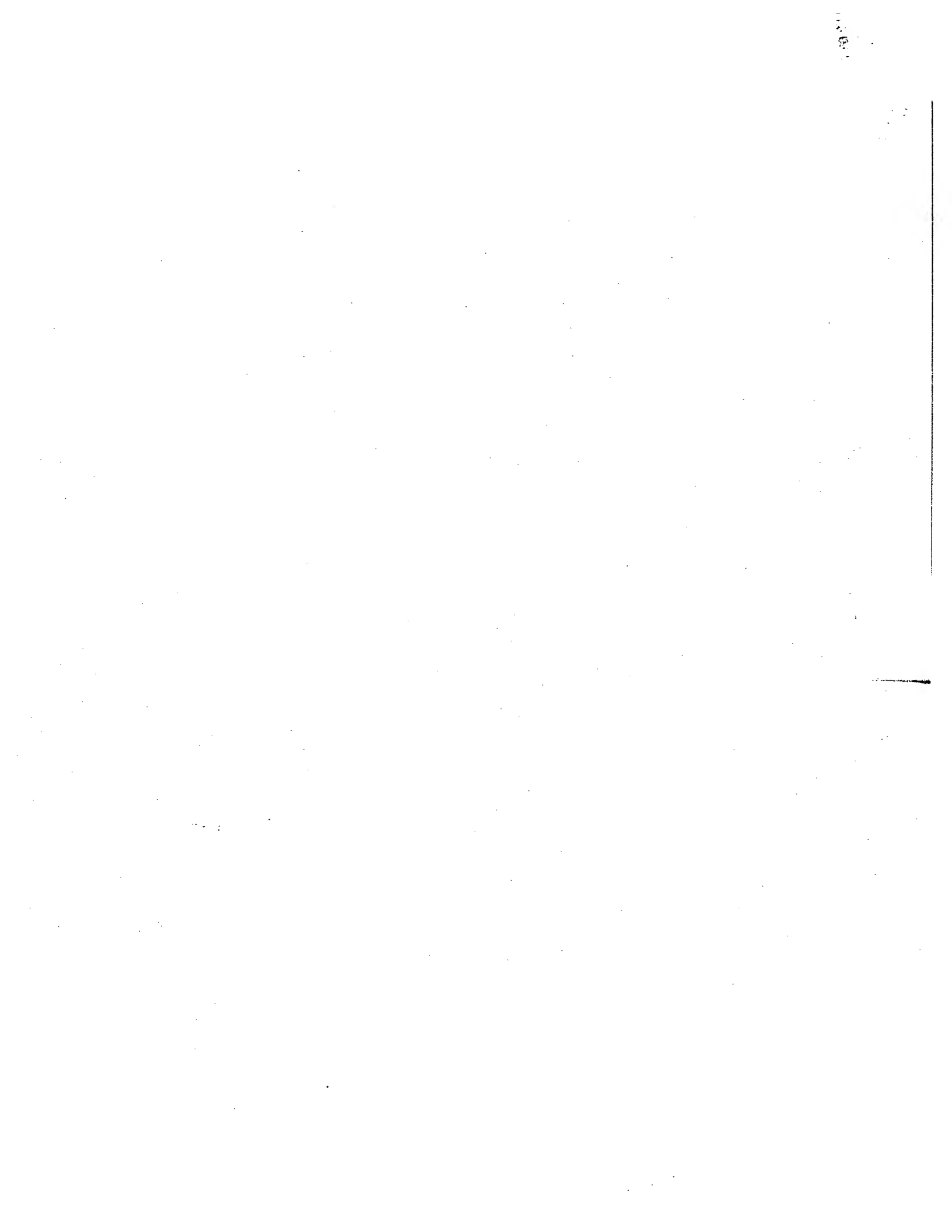
**INTERNATIONAL SEARCH REPORT**

Information on patent family members

Int. Application No

PCT/US 95/13680

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR-A-2699810	01-07-94	AU-B- 5818194 WO-A- 9414389	19-07-94 07-07-94
FR-A-2652267	29-03-91	NONE	
GB-A-2276325	28-09-94	US-A- 5370657 CA-A- 2119814 DE-A- 4410256 FR-A- 2702953	06-12-94 27-09-94 29-09-94 30-09-94
FR-A-2573646	30-05-86	CA-A- 1255176 EP-A,B 0188927 US-A- 4688553	06-06-89 30-07-86 25-08-87
US-A-5059205	22-10-91	US-A- 5242462	07-09-93





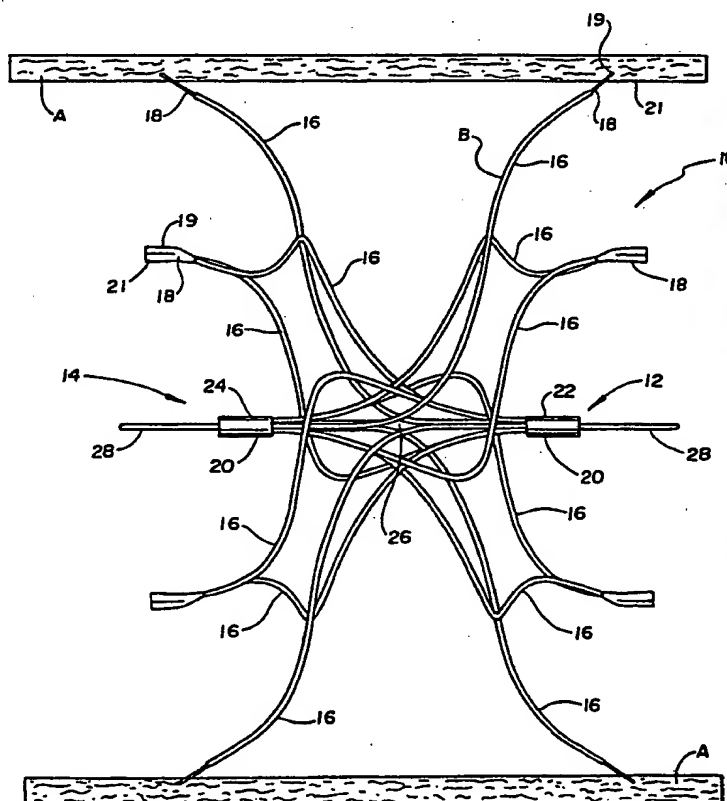
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/US95/13680 (22) International Filing Date: 25 October 1995 (25.10.95) (30) Priority Data: 08/328,629 25 October 1994 (25.10.94) US (71) Applicant: SCIMED LIFE SYSTEMS, INC. [US/US]; One Scimed Place, Maple Grove, MN 55311-1566 (US). (72) Inventor: SMITH, Scott, R.; 6950 County Road 10, Chaska, MN 55318 (US). (74) Agents: GAFNER, Peter, J. et al.; One Scimed Place, Mail Stop A150, Maple Grove, MN 55311-1566 (US).		(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  Published <i>With international search report.          Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: REMOVABLE THROMBUS FILTER

## (57) Abstract

A thrombus filter configured for placement within a blood vessel lumen. The filter having a longitudinal axis. The filter includes first and second units, each unit including a plurality of elongated struts. Each strut has a joining end where the respective struts of each unit are joined together. Each strut also has a free end opposite the joining end. The struts have at least two curves such that in a longitudinal planar projection of the filter, each strut has a first direction of curvature proximate the joining end and an opposite direction of curvature closer to the free end. In a transverse planar projection of the filter, the strut has a first direction of curvature proximate the joining and an opposite direction of curvature closer to the free end. The units can be coupled together in opposition such that the free ends of the struts of the first unit are generally oriented in a first longitudinal direction and the free ends of the struts of the second unit are generally oriented in the opposite longitudinal direction.



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## REMOVABLE THROMBUS FILTER

Background of the Invention

The present invention pertains to thrombus filters. In particular, the present invention relates to thrombus filters which can be securely affixed at a selected location in the vascular system and removed when no longer required.

In recent years, pulmonary embolism has become an increasingly common medical emergency. Pulmonary embolisms may be caused by venous thrombosis, which in turn may be caused by blood flow retention, venous intima damage or coagulation abnormalities. Emergency or prophylactic treatments for these conditions includes anti-coagulant therapy, thrombolytic therapy, thrombectomy and inferior vena cava blocking procedures.

Among these therapeutic options, when an inferior vena cava blocking procedure is selected, one option is to perform a laparotomy under general anesthesia during which the inferior vena cava is ligated, sutured and shortened, or clipped. A laparotomy however, requires a general anesthetic and is susceptible to thrombosis formation due to the discontinuation of anti-coagulate therapy prior to surgery. Another option is to intravenously insert a thrombus filter into the inferior vena cava which requires a local anesthetic. Percutaneous filter insertion is now widely employed since it requires only a local anesthetic. However, such filters become affixed in the inner vena cava wall by neointimal

hyperplasia within two or three weeks after being implanted, after which they cannot be removed percutaneously.

Prior thrombus filters which may be removed percutaneously have included generally linear or column-like  
5 struts which tend to transfer forces along the longitudinal axis of the struts. If the vessel is compressed asymmetrically, the filter elongates forcing the struts into the vessel wall which may damage the vessel.

10

#### Summary of the Invention

The present invention pertains to an improved thrombus filter having struts configured to reduce the transmission of force along their longitudinal axes. The filter in accordance with the present invention provides struts which behave more  
15 as cantilevered beams than those filters which have struts tending to transfer forces primarily along the struts' longitudinal axes.

In an embodiment of the thrombus filter for placement within a blood vessel lumen, in accordance with the present  
20 invention, the filter includes a longitudinal axis. The filter also includes first and second units, each unit including a plurality of elongated struts. Each strut has a joining end where the respective struts of each unit are joined together. Each strut has a free end opposite the  
25 joining end. The struts extend generally radially outward

from the longitudinal axis of the filter and generally longitudinally.

Each strut has at least two curves such that in a longitudinal planar projection of the filter each strut has a  
5 first direction of curvature proximate the joining end and an opposite direction of curvature closer to the free end. In a transverse planar projection of the filter, each strut has a first direction of curvature proximate the joining end and an opposite direction of curvature closer to the free end.

10 The first and second units are coupled together in opposition such that the free ends of the struts of the first unit are generally oriented in a first longitudinal direction and the free ends of the struts of the second unit are generally oriented in the opposite longitudinal direction.  
15 Several couplings are available to releasably couple the first and second units together.

The free ends of the struts can include a sharpened anchoring tip and an adjacent flexible pad. The filter may also include a stream lining sheath covering the struts  
20 proximate the joining ends to reduce intraluminal blood flow turbulence.

#### Description of the Drawings

Figure 1 is perspective view of a filter in accordance  
25 with the present invention;

Figure 2 is side view of the filter in accordance with the present invention;

Figure 3 is an end view of the filter in accordance with the present invention;

5      Figure 4 is a cross sectional view of a coupling for coupling first and second units of the filter together;

Figure 5 is a cross sectional view of an alternate embodiment of the coupling for coupling the first and second units of the filter together;

10      Figure 6 is cross sectional view of another alternate embodiment of the coupling for coupling the first and second unit of the filter together;

Figure 7 is a cross sectional view of yet another alternate embodiment of the coupling for coupling the first  
15 and second units of the filter together;

Figure 8 is perspective view of a free end of a strut of the filter made in accordance with the present invention;

Figure 9 is a perspective view of an alternate embodiment of the free end of the strut of the filter made in accordance  
20 with the present invention;

Figure 10 is side view of an alternate embodiment of the filter in accordance with the present invention including stream lining;

Figure 11 is a transverse cross sectional view of a hub  
25 in accordance with the present invention; and

Figure 12 is a transverse cross sectional view of an alternate hub in accordance with the present invention.

Detailed Description of Drawings

5 Referring now to the drawings wherein like reference numerals refer to like elements throughout the several views, Figure 1 shows a perspective view of a thrombus filter in accordance with the present invention and generally referred to by the numeral 10. Thrombus filter 10 includes first and  
10 second units 12 and 14, respectively. Each unit 12 and 14 includes a plurality of struts 16. Each strut includes a free end 18 and a joining end 20. Free ends 18 include a sharpened portion 19 and an adjacent flexible pad portion 21. The joining ends 20 of struts 16 of first unit 12 are joined at a  
15 hub 22 and the joining ends 20 of the respective struts 16 of second unit 14 are joined at a hub 24. Hubs 22 and 24 are generally aligned along the longitudinal axis of the filter and are fastened together by coupling 26.

Struts 16 of first unit 12 generally radiate from hub 22  
20 away from the longitudinal axis of filter 10 and longitudinally in a direction toward hub 24 of second unit 14. Similarly, struts 16 of second unit 14 generally radiates from hub 24 away from the longitudinal axis of filter 10 and generally longitudinally toward hub 22 of first unit 12.  
25 Thus, first unit 12 is coupled in opposition to second unit 14 such that free ends 18 of struts 16 of first unit 12 are

generally oriented in the opposite direction from free ends 18 of struts 16 of second unit 14.

Filter 10 also preferably includes two oppositely disposed hooks 28. One hook 28 is attached to hub 22 of first unit 12 and generally extend longitudinally in the opposite direction as struts 16 of first unit 12. Likewise, hook 28 of second unit 14 is connected to and extends from hub 24 and generally longitudinally in the opposite direction as struts 16 extends from hub 24.

Filter 10 may be compressed elastically in a transversed direction and placed in a sheath or catheter lumen. After compression, filter 10 may be delivered to a deployment cite within a vessel lumen by percutaneous catheterization. Within the catheter, the longitudinal axis of filter 10 is generally aligned with, or approximately parallel to the longitudinal axis of the vessel lumen. When the distal end of the catheter reaches the deployment site within the vessel lumen, compressed filter 10 is released from the sheath or catheter where it expands transversely until the free ends 18 of strut 16 reach the side wall of the vessel lumen.

To allow filter 10 to undergo transverse elastic compression, struts 16 are preferably formed from nitinol wire. Other shaped memory alloy wires and super elastic metal wires may be used as well as stainless steel, tungsten, platinum, and chromium alloy wires. In a preferred embodiment, struts 16 are formed from 0.011 inch diameter

nitinol wire having a portion proximate free ends 18 having a diameter of 0.015 to improve visibility and strength, and a portion proximate joining end 20 having a diameter of between 0.012 to 0.015 inch to improve strength and fatigue performance at the hubs 22 and 24. It can be appreciated that the diameter of the wire can be varied according to the type of wire used and the particular configuration of filter 10. The wires can be formed by heat setting within a rigid mold as well as by other methods known in the art.

Struts 16, in accordance with the present invention have been configured to respond more like cantilevered beams than as columns. That is, significant bending and torsional forces are distributed along struts 16, rather than forces being primarily transmitted along the longitudinal axes of struts 16. By configuring struts 16 to act more as cantilevered beams rather than as columns, it is believed that the struts will act more independently. By acting independently, struts 16 transmit less force to hubs 22 and 24 and other struts 16, especially those forces tending to rotate filter 10 transversely within a vessel lumen.

Several criteria are taken into account in the design of struts 16. Each strut 16 should be configured and formed of material which enables struts 16 to be collapsed for delivery to a deployment location within a vessel lumen. Struts 16, however, should not produce transverse or longitudinal forces which are so great that free ends 18 of struts 16 damage the

vessel wall. Upon deployment of filter 10, struts 16 should be spaced closely enough to intercept thrombus within the range of about 3.0 millimeters to 3.0 centimeters in length, yet not obstruct the vessel so much that excess turbulence is created. Excess turbulence can lead to the formation of additional thrombus. To allow percutaneous removable of filter 10, struts 16 should be configured so that they have a minimum of contact with the vessel wall even when the vessel is compressed axially or radially. If struts 16 come in contact with the vessel wall for an extended period of time neointimal hyperplasia can grow over struts 16, embedding them in the vessel wall. The length and diameter of filter 10 must also be appropriate to the particular application. For example, when deploying filter 10 within the inferior vena cava between the iliac vein and the renal vein, the typical length of the uncompressed filter can be between about 3.0 to 4.0 centimeters in length and about 1.5 to 3.5 centimeters in diameter.

Figure 2 shows a side view of a filter 10 deployed within a vessel lumen A. For purposed of describing the shape of strut 16, it is assumed that vessel lumen A is cylindrical and that the longitudinal axis of vessel lumen A is coincident with the longitudinal axis of filter 10. In particular, this view is a longitudinal planar projection of filter 10 within lumen A. As can be seen with particular clarity by reference to the strut 16 labeled with a "B", the strut has at least two



curves such that in the longitudinal planar projection of the filter the strut has a first direction of curvature proximate joining end 20 and an opposite direction of curvature closer to free end 18. In particular, the strut 16 referred to by  
5 the letter "B" extends from hub 24 generally longitudinally and then curves in a transverse direction away from the longitudinal axis of filter 10. The strut 16 then curves in a longitudinal direction away from hub 24 closer to free end 18 of strut 16. Strut 16 as shown in Figure 2 begins to  
10 immediately curve transversely from hub 24. Strut 16 may, however, first extend longitudinally from hub 24 prior to curving transversely.

In view of the perspective from which struts 16 are viewed in Figure 2, they appear to have various shapes.  
15 Struts 16, as shown in Figure 2, however, are in fact generally the same shape. For convenience of manufacture, each of the struts may be formed in the same shape, but in accordance with the present invention, they need not so long as the curvature of struts 16 provides the desired performance  
20 characteristics.

Preferably, first unit 12 includes six struts 16 and second unit 14 include six struts 16. Fewer or more struts per unit may be used in accordance with the present invention. Varying the number of struts can, however, affect the ability  
25 of filter 10 to filter thrombus from the vessel and to retain its position within the vessel.

As shown in Figure 2, sharpened portions 19 of strut free ends 18 penetrate the wall of vessel lumen A. Further penetration is resisted by pads 21 abutting the vessel wall.

Figure 3 is an end view of filter 10 deployed within the vessel A. Specifically, Figure 3 shows a transverse planar projection of an end of filter 10. As can be seen, each of the six struts 16 of first and second units 12 and 14, respectively are disposed around the longitudinal axis of filter 10 at approximately even 60 degree intervals. In this view, each strut 16 has a first direction of curvature proximate hubs 22 and 24 respectively and an opposite direction of curvature closer to free ends 18. In particular, each strut 16 extends transversely from the longitudinal axis, then curves in a spiral-like fashion in a first direction (not necessarily the same direction) generally around the longitudinal axis of filter 10. Closer to free ends 18 of struts 16, struts 16 curve in a direction opposite the first direction relative to the longitudinal axis of filter 10.

In view of the complexity of the geometry of each strut 16, the following table is provided to define a typical strut 16 in cylindrical coordinates. Each row in the table defines a point along the center line of strut 16, the point in the first row being at the extreme joining end 20 of strut 16 and point in the last row being at the extreme free end 18 of strut 16. Each of the remaining rows identify intermediate points along a center line of strut 16. It should be

appreciated, however, that the strut 16 defined by the tabulated coordinates is representative only and that numerous alternate geometric configurations may be made in accordance with the present invention.

5       Cylindrical coordinates are an extension of two dimensional polar coordinates to include a third or longitudinal dimension Z. When describing the typical strut 16 in the table, the longitudinal or Z axis of the cylindrical coordinates has been chosen to be coincident with the  
10 longitudinal axis of filter 10. In the table, the first column is the radial distance R in inches from the Z axis to the center line of strut 16. The second column is the angular distance  $\theta$  from a reference line and the third column is linear distance Z perpendicular to a plane including the  
15 referenced line. The coordinates in the table assume an initial radial offset of joining end 20 from the longitudinal axis of 0.011 inches.

	R	$\theta$	Z
	0.011000	0.000000°	0.000000
20	0.011000	0.000000°	0.025000
	0.025000	0.000000°	0.100000
	0.025000	10.374822°	0.250000
	0.452243	54.969992°	0.250000
	0.669958	90.000000°	0.553000
25	0.730495	90.000000°	0.636188

Figure 4 shows a side view of coupling 26. Coupling 26 includes a first wire 30 extending generally longitudinally from hub 24 of second unit 14 toward hub 22 and a second wire 32 extending generally longitudinally from hub 22 of first unit 12 toward hub 24. An end of wire 30 opposite hub 22 is formed into a helix or coil 34. Similarly, an end of wire 32 opposite hub 24 is formed into a coil or helix shape 36. A portion of wire 30 extends through helix 36 and a portion of wire 32 extends through helix 34 to couple wires 30 to wire 32 and consequently first unit 12 to second unit 14 respectively. Coils 34 and 36 must be rigid enough to resist premature uncoupling and flexible enough to uncouple when hooks 28 are pulled in opposite longitudinal directions.

Figure 5 shows an alternate coupling 40. Coupling 40 includes a first wire 42 extending from hub 22 of first unit 12 like wire 30. Coupling 40 includes a second wire 44 extending from hub 24 of second unit 14 similarly to wire 32. A tube 46 is attached, by adhesive or other suitable means, to an end of wire 42 opposite hub 22. Tube 46 may include a crimp 48 resiliently engageable with a narrowed portion 50 of wire 44. Alternately, tube 46 may include an expanded portion engageable with an expanded end of wire 44. Tube 46 must be rigid enough to prevent premature uncoupling, however, tube 46 must be flexible enough to allow wire 44 to be removed from tube 46 when hooks 28 are pulled in opposite longitudinal directions.

Figure 6 is a cross sectional view of another alternate coupling 52 taken along the longitudinal axis of the filter. Coupling 52 includes a first wire 54 extending from hub 22 of first unit 12 longitudinally toward hub 24 of second unit 14 and a second wire 56 extending longitudinally from hub 24 of second unit 14 toward hub 22. A tube 58 is attached by adhesive or other suitable means to an end of wire 54 opposite hub 22. A notch 60 extends through a side wall of tube 58. Wire 56 includes a bend 61 which can resiliently engage notch 60 when wire 56 is inserted into tube 58. Coupling 52 may be uncoupled by pulling hooks 28 in an opposite longitudinal direction. Wires 54 and 56 and tube 58 should be sufficiently strong to resist premature uncoupling. They may, for example, be made from stainless steel or a similarly durable material. Wire 56 must be resilient enough to engage notch 60 when wire 56 is inserted into tube 58, but rigid enough that premature uncoupling is avoided.

Figure 7 shows still another alternate embodiment of a coupling 62. Coupling 62 includes a first wire 64 extending generally longitudinally from hub 22 of first unit 12 toward hub 24 of second unit 14, and a wire 66 extending from hub 24 generally longitudinally toward hub 22. The end of wire 64 opposite 22 and the end of wire 66 opposite hub 24 overlap and are coupled by a heat shrink wrap 68, such as polytetrafluoroethylene (PTFE). An adhesive 70 bonds heat shrink wrap 68 to wire 66. When hooks 28 of hubs 22 and 24

are pulled in opposite directions, wire 64 is pulled away from wire 66 and shrink wrap 68. Heat wrap 68 remains adhered to wire 66. Shrink wrap 68 must be sufficiently strong and adhesive to prevent premature uncoupling of wires 64 and 66.

5        Figure 8 is a perspective view of free end 18 of strut 16 including sharpened portion 19 and adjacent flexible pad portion 21. Sharpened portion 19 and pad 21 may be formed integrally with strut 16. This may be accomplished, by, for example, flattening free end 18 of strut 16. Flattened free  
10 end 18 can be divided by cutting it into two portions. One of the portions can be further cut to form sharpened portion 19 and the other portion bent toward the longitudinal axis of filter 10 to form pad 21. It can be appreciated that other techniques may be used in accordance with the present  
15 invention to form integral sharpened portion 19 and pad 21. Further, it should be understood that sharpened portion 19 and pad 21 may be formed separately and subsequently connected to free end 18 of strut 16 by adhesive, welding or other suitable means.

20        Figure 9 shows an alternate embodiment of free end 18 of strut 16 which includes a sharpened portion 72 and pad 74. Sharpened portion 72 and pad 74 can be formed as discussed in the preceding paragraph with respect to sharpened portion 19 and pad 21. Pad 74 is preferably more flexible than sharpened  
25 portion 72. This may be accomplished by, for example, flattening pad 74 more than sharpened portion 72. Pad 74 is

also preferably longer than sharpened portion 72. When unstressed, pad 74 can lie in the same plane as portion 72.

Figure 10 shows filter 10 including a stream lined encapsulation covering 76 over a portion of struts 16 proximate the longitudinal axis of filter 10. Stream lining of this region of filter 10 is intended to reduce the turbulence near the longitudinal axis of filter 10. The stream lined encapsulation 76 must be formed from a material which is sufficiently durable to survive expansion and contraction of filter 10, yet flexible enough to allow independent flexing of struts 16. Stream line encapsulation 76 may be formed from a heparin loaded collagen, low durometer polyurethane or other similarly suitable material.

Figure 11 is a transverse cross sectional view of hub 22, which is essentially similar to hub 24. As shown in Figure 11, joining ends 20 of struts 16 are arranged around hook 28 within a tube 78. It should be noted that hook 28 may be an integral extension of wire 30 of coupling 26. Wire 32 of coupling 26 of hub 24 and the other coupling wires of the alternate coupling embodiments may be similarly integrally formed. If these corresponding wires are not integrally formed an end of each wire can extend into the respective hub to be joined with joining ends 20 like hook 28 shown in Figure 11. Tube 78 can be a hypotube or other similarly suitable member. Within tube 78 joining ends 20 and hook 28 may be

welded together, crimped, diffusion bonded, press fit, swagged or held together by other suitable means.

Figure 12 is a transverse cross sectional view of an alternate embodiment of hub 22 including a tubular member 80 which has been compressed around joining ends 20 of strut 16 and hook 28. Compression of tube 80 causes a deformation of the circular cross sections of ends 20 and hook 28 to form an abutting planar sides between ends 20 and hook 28. Like the embodiment of hub 22 described in the previous paragraph, the respective hooks and wires may be formed integrally or separately and attached to hub 22 accordingly. Any of the joining methods mentioned above such as welding may be used in addition to compressing tube 80.

In use, it is important to measure the inside diameter of the patient's vessel so that a filter having the appropriate diameter is selected. If a filter is undersized there is a risk that it could migrate within the vessel lumen. If filter is oversized it may put undue stress on the vessel wall. A filter having an unstressed diameter equal to approximately 1.3 times the diameter of the vessel into which it is planted has been found to be desirable. This ratio is exemplary only, it being understood that the actual ratio will depend on the particular configuration of struts 16 and the material used to form them.

The thrombus filter can be delivered to a deployment site within a vessel lumen by compressing the filter into a sheath



or a catheter lumen. The distal end of the catheter is manipulated to a location within the patient's vessel where the filter 10 is to be deployed such that the longitudinal axis of filter 10 is generally coincident or parallel to the longitudinal axis of the vessel. Filter 10 is then urged from the distal end of the catheter lumen into the patient's vessel lumen. Upon release from the catheter lumen, strut 16 expands generally transversely to the longitudinal axis of filter 10 such that sharpened portions 19 penetrate the vessel lumen wall while pads 21 limit the extent of the penetration.

When it becomes necessary or desirable to remove the filter, the following procedure can be followed. Recovery devices can be inserted percutaneously and threaded through endovenous routes to opposite ends of filter 10. The devices must include means for attaching to hooks 28, such as clamps, loops, hooks, or similar means. One device is attached to each hook 28 and the devices are withdrawn in opposite directions such that first and second units 12 and 14 are pulled apart and uncoupled from each other. First and second units 12 and 14 respectively are then withdrawn from the body.

Numerous characteristics and advantages of the invention covered by this document have been set forth in the foregoing description. It will be understood, however, that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of parts without exceeding the scope of

the invention. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. A thrombus filter configured for placement within a blood vessel lumen, and having a longitudinal axis, the filter comprising:

first and second units, each unit including a plurality of elongated struts, each strut having a joining end where the respective struts of each unit are joined together, each strut having a free end opposite the joining end, and each strut having at least two curves such that in a longitudinal planar projection of the filter each strut has a first direction of curvature proximate the joining end and an opposite direction of curvature closer to the free end; and

the units are coupled together in opposition such that the free ends of the struts of the first unit are generally oriented in a first longitudinal direction and the free ends of the struts of the second unit are generally oriented in the opposite longitudinal direction.

2. A filter in accordance with claim 1, wherein, in a transverse planar projection of the filter, the strut has a first direction or curvature proximate the joining end and an opposite direction of curvature closer to the free end.

3. A filter in accordance with claim 1, wherein the free end of the strut includes a sharp anchoring tip and an adjacent flexible pad.

4. A filter in accordance with claim 1, further comprising a sheath covering the struts proximate the joining ends providing stream lining of the filter to reduce intraluminal blood flow turbulence.

5. A thrombus filter for placement within a blood vessel lumen, having a longitudinal axis, the filter comprising:

first and second units, each including a plurality of a elongated struts, each strut having a joining end and a free end, wherein the respective struts of each unit are joined together generally about the longitudinal axis of the filter at the joining ends;

each strut of the first unit extends from the joining end in generally the same longitudinal direction and then curves in a transverse direction away from the longitudinal axis and then curves in a longitudinal direction closer to the free end;

each strut of the second unit extends from the joining end in generally the same longitudinal direction and then curves in a transverse direction away from the longitudinal

axis and then turns in a longitudinal direction closer to the free end; and

the first and second units being coupled in opposition such that the free ends of the first unit struts are generally oriented in a first longitudinal direction and the free ends of the second unit struts are oriented generally in the opposite direction.

6. A filter in accordance with claim 5, wherein as each strut extends transversely from the longitudinal axis, the strut curves in a spiral-like fashion in a first direction generally around the longitudinal axis of the filter.

7. A filter in accordance with claim 6, wherein closer to the free end of the struts, the strut curves in a direction opposite the first direction relative to the longitudinal axis of the filter.

8. A filter in accordance with claim 5, wherein the free end of the strut includes a sharp anchoring tip and adjacent flexible pad.

9. A filter in accordance with claim 5, further comprising a sheath covering the struts proximate the joining ends providing streamlining of the filter to reduce intraluminal blood flow turbulence.

10. A thrombus filter for placement within a blood vessel, having a longitudinal axis, the filter comprising:

first and second units, each including a plurality of elongated struts, each strut having a joining end and a free end, wherein the respective struts of each unit are joined together generally about the longitudinal axis of the filter at the joining ends;

each strut of the first unit extends from the joining end in generally the same longitudinal direction and then curves in a transverse direction away from the longitudinal axis;

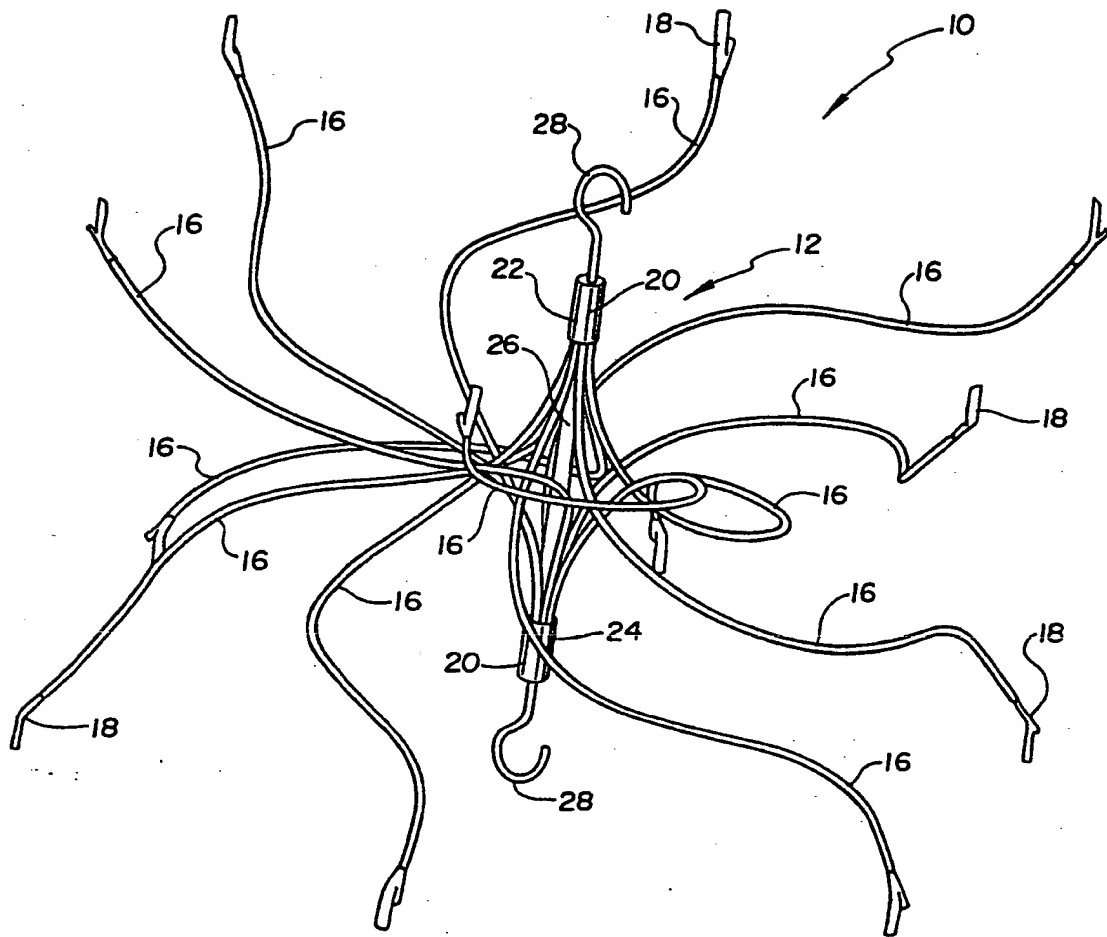
each strut of the second unit extends from the joining end in generally the same longitudinal direction and then curves in a transverse direction away from the longitudinal axis; and

the first and second units being coupled in opposition such that the free ends of the first unit struts are generally oriented in a first longitudinal direction and the free ends of the second unit struts are oriented generally in the opposite direction.

11. A filter in accordance with claim 10, wherein as each strut extends transversely from the longitudinal axis, the strut curves in a spiral-like fashion in the first direction generally around the longitudinal axis of the filter.

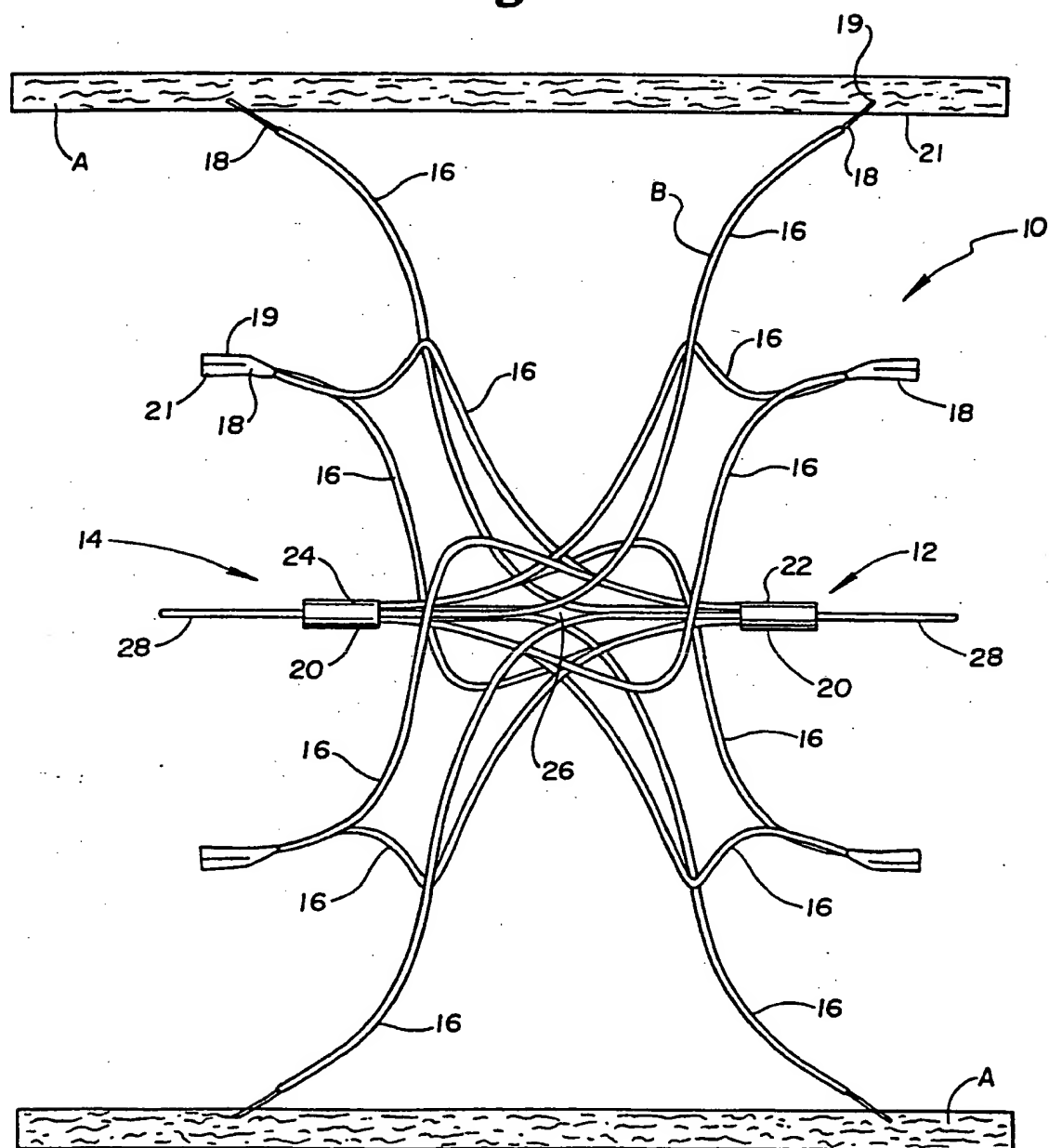
12. A filter in accordance with claim 11, wherein closer to the free end of the struts, the strut curves in a direction opposite the first direction relative to the longitudinal axis of the filter.

**Fig. 1**



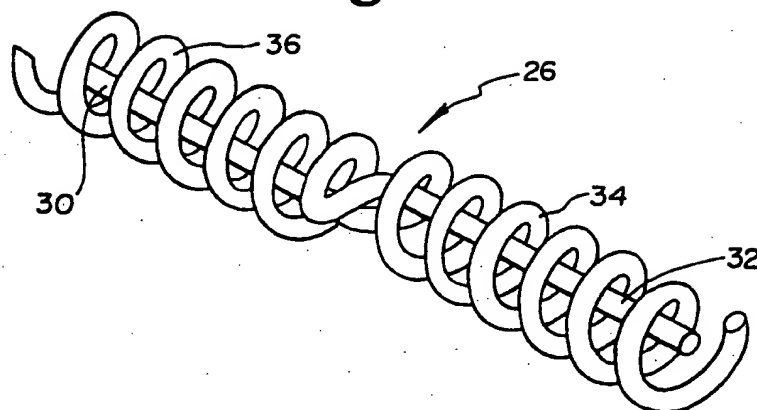
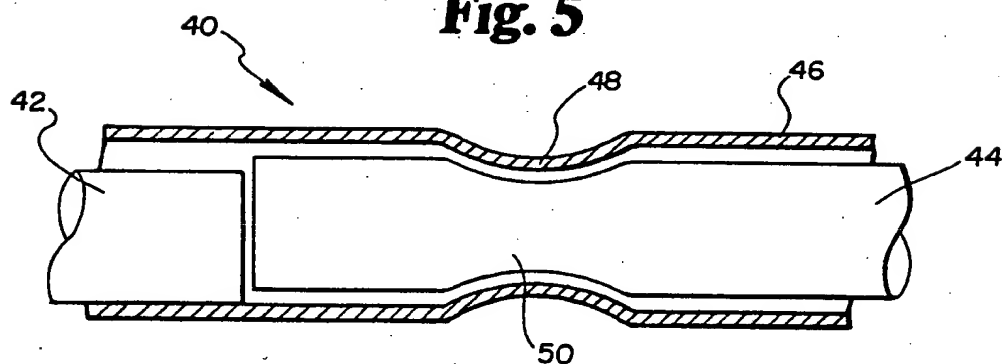
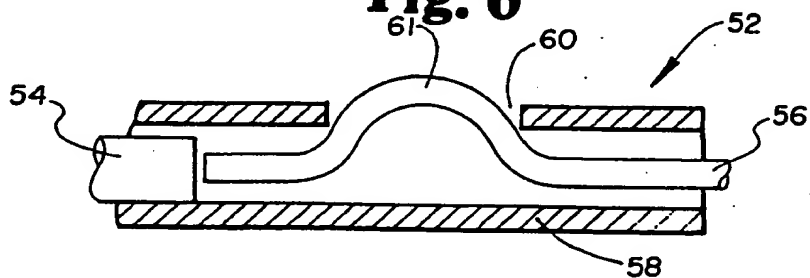


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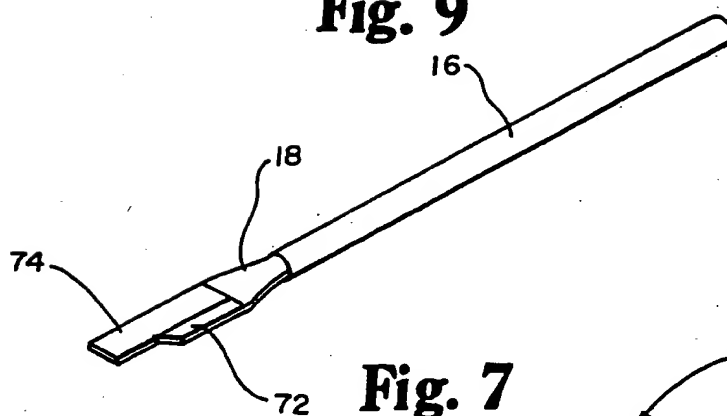
**Fig. 2**



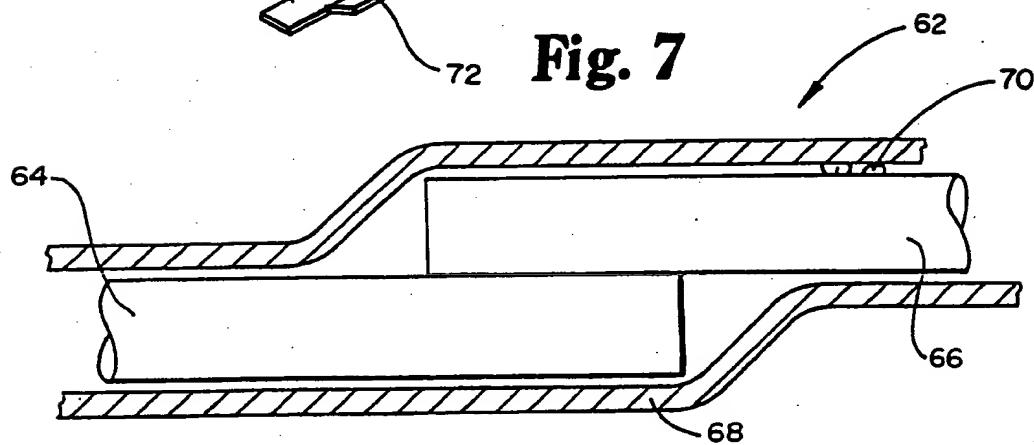
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**Fig. 4****Fig. 5****Fig. 6**

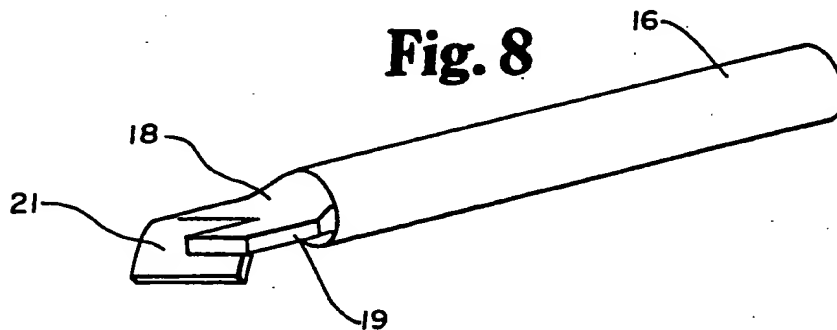
**Fig. 9**



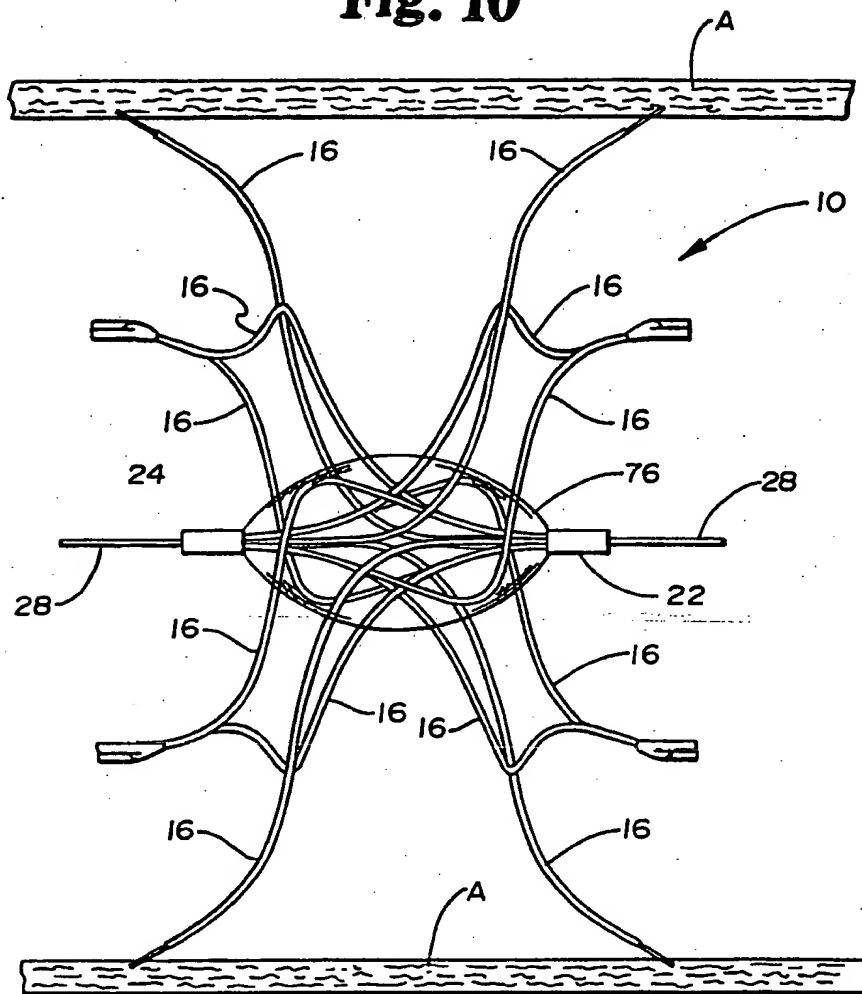
**Fig. 7**



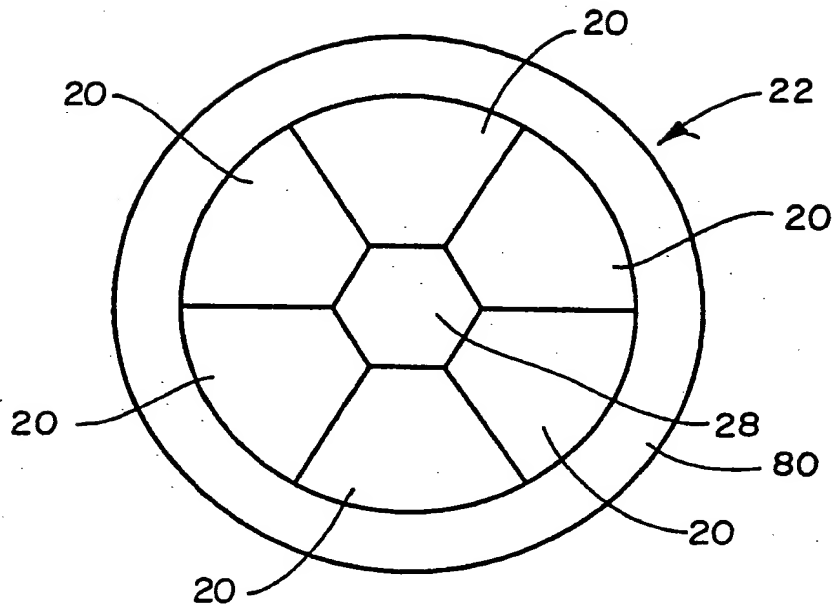
**Fig. 8**



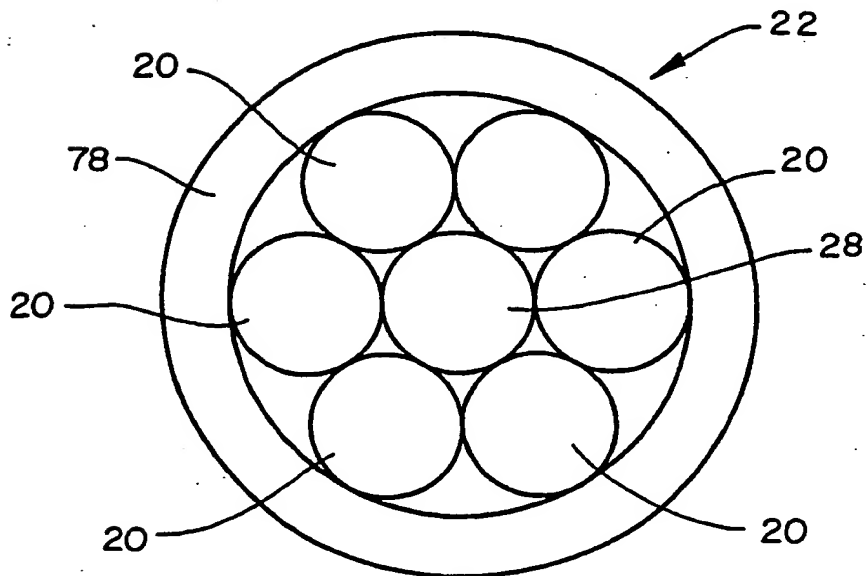
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**Fig. 10**

**Fig. 12**



**Fig. 11**



# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 95/13680

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 6 A61F2/01

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	FR,A,2 699 810 (CARDIAL) 1 July 1994 see page 3, line 15 - page 4, line 10; figures	1-12
Y	FR,A,2 652 267 (PROTHIA) 29 March 1991 see page 6, line 21 - line 24; figures 4,6	1-12
A	GB,A,2 276 325 (SCIMED LIFE SYSTEMS) 28 September 1994 see abstract	1,4,5,9, 10
A	FR,A,2 573 646 (CELSA) 30 May 1986 see figures 7-10	1-3,5,8, 10,12
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

16 February 1996

Date of mailing of the international search report

07. 03. 96

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International Application No  
PCT/US 95/13680

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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International Application No

PCT/US 95/13680

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